In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 14-748V
Filed: December 2, 2015

* *	UNPUBLISHED
NICOLE SOLOMON, *	
*	Chief Special Master Nora Beth Dorsey
Petitioner, *	
*	Entitlement; Ruling on the Record;
v. *	Decision Without a Hearing; Lack of a
*	Medical Opinion; Insufficient Proof of
*	Causation; Fibromyalgia;
SECRETARY OF HEALTH *	Guillain-Barré Syndrome ("GBS")
AND HUMAN SERVICES, *	Special Processing Unit ("SPU")
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Amber Wilson, Maglio Christopher and Toale, PA, Washington, DC, for petitioner.
Julia McInerny, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

On August 19, 2014, Nicole Solomon ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, et seq.,[2] [the "Vaccine Act" or "Program"]. Petitioner alleges she suffered symptoms of dizziness, numbness, fatigue, tingling, and pain after receiving the

[1] Because this unpublished decision contains a reasoned explanation for the action in this case, the undersigned intends to post this decision on the website of the United States Court of Federal Claims, in accordance with the E-Government Act of 2002 § 205, 44 U.S.C. § 3501 (2006). In accordance with the Vaccine Rules, each party has 14 days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted ruling. If, upon review, the undersigned agrees that the identified material fits within the requirements of that provision, such material will be deleted from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

influenza vaccine on September 20, 2011 and the tetanus, diphtheria, and pertussis ("TDP") vaccine on October 6, 2011. Petition at 1-2. Petitioner further alleges that her symptoms are "believed to be consistent with Guillain-Barre Syndrome" (id., ¶ 6) and that her injuries are "causally connected to an adverse reaction" to her vaccinations (id., ¶ 8). The case was assigned to the Special Processing Unit of the Office of Special Masters.

Under the Vaccine Act, compensation may not be awarded "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." § 13(a)(1). Petitioner has failed to file the report of a medical expert, and the medical records do not support petitioner's claims. For the reasons discussed below, petitioner has failed to demonstrate that she is entitled to compensation. The petition is dismissed for insufficient proof.

I. Procedural History

Petitioner indicated she filed her petition on August 19, 2014, without all relevant medical records due to the impending expiration of the Vaccine Act's statute of limitations. Petition, ¶ 2. The next day, she filed some medical records. See Exhibits 1-8 (ECF No. 5). She was allowed additional time to file the remaining records. See Non-pdf Order, issued Sept. 4, 2014.

During the following month, petitioner continued to file medical records. See Exhibits 9-14 (ECF Nos. 8, 10-11). The initial status conference was held telephonically on September 30, 2014. During the call, the parties discussed the time needed for petitioner to file her remaining medical records and for respondent to file a status report providing her tentative position regarding petitioner's claim. See Order at 1 (ECF No. 13). After the call, petitioner filed one more document (her affidavit) on November 3, 2014. See Exhibit 15 (ECF No. 14). On December 1, 2014, petitioner indicated she had completed her filings. See Statement of Completion (ECF No. 17).

On December 21, 2014, respondent filed a status report indicating her belief that "settlement discussions [were] not appropriate." Status Report at 1 (ECF No. 19). Respondent argued that "petitioner's correct diagnosis is fibromyalgia syndrome and not Guillain-Barre Syndrome." Id.

On January 29, 2015, respondent filed her Rule 4(c) report asserting that petitioner's claim should not be compensated. Rule 4(c) Report at 1 (ECF No. 21). Respondent again argued that petitioner has not established that she suffered from Guillain-Barré Syndrome ("GBS") adding that she had not proven her vaccinations caused her alleged injury, whether categorized as "GBS, fibromyalgia or any other condition." Id. at 7. Petitioner was ordered to file the report of a medical expert. See Order at 1 (ECF No. 22).

Over the next five months, petitioner filed three motions for additional time to file an expert report. Shortly after the first and second motions, petitioner filed updated

medical records and a letter from one of her treating physicians.[3] Petitioner did not file an expert report as ordered.

Instead, on July 21, 2015, petitioner filed a motion for a decision on the record pursuant to Vaccine Rule 8(d).[4] In her motion, petitioner indicated she "has filed all relevant medical records and affidavits pertaining to this Petition and considers the evidentiary record closed." Motion for a Decision on the Record at 1 (ECF No. 30). She further indicated that she "will not proffer the opinion of a medical expert in support of vaccine causation of the injury alleged, and consequently elects not to pursue a formal causation hearing with expert witness testimony." Id. at 2.

Respondent filed her response approximately one month later (on August 24, 2015). Respondent argued that petitioner's claim should not be compensated and instead, should be dismissed. Response at 6 (ECF No. 32).

The matter is now ripe for adjudication.

II. Medical History

The medical records from petitioner's primary care physician, Dr. Karen Wendowski, consist mainly of Dr. Wendowski's copy of records from other providers. See Exhibit 14. The only record discussing a visit to Dr. Wendowski describes a sick visit for sinusitis on October 27, 2009. See id. at 20. Petitioner's condition prior to the vaccinations alleged as causal can be gleaned from the other medical records filed.

The medical records from petitioner's allergist, Dr. Wise, show petitioner suffered frequent upper respiratory infections ("URIs") since childhood. See Exhibit 7 at 15. She has undergone back and sinus surgeries,[5] has experienced an adverse reaction (hives)

[3] See Exhibits 16-17 (ECF Nos. 24, 28). Approximately one week after her first motion for additional time (on April 8, 2015), petitioner filed updated medical records from her allergist, Dr. Steven L. Wise. See Exhibit 16 (ECF No. 24). Approximately one month after her second motion for additional time (on June 30, 2015), petitioner filed a letter from a neurologist, Dr. Cynthia K. McGarvey, whom she first saw in November 2013 (two years after receiving the alleged causal vaccinations). See Exhibit 17 (ECF No. 28). Because these documents contain statements from petitioner's treating physicians regarding her injury, its cause, and the need to avoid future influenza vaccinations, the undersigned will discuss their contents further in Sections II and IV.

[4] The Vaccine Rules, which can be found at Appendix B to the Rules of the Court of Federal Claims ("RCFC"), govern all Vaccine Act proceedings. Vaccine Rule 1(a). Under the Vaccine Rules, a special master may "decide a case on the basis of written submissions without conducting an evidentiary hearing." Vaccine Rule 8(d).

[5] See Exhibits 6 at 2; 7 at 10, 15; 13 at 86. The medical records indicate petitioner underwent a tonsillectomy and adenoidectomy in 1983 (when 10 years old) and sinus

to sulfa drugs, and has "a history of Bell's palsy on the right [side] with some slight residual weakness." Exhibit 7 at 15.

On May 4, 2010, approximately 18 months prior to the alleged causal vaccinations (in May 2010), petitioner was seen by her gynecologist for excessive and frequent menstruation. Exhibit 6 at 22. Around that same time, allergy testing revealed petitioner suffered from a "significant mold allergy," and she began receiving injections for allergen immunotherapy. Exhibit 7 at 15. Approximately one year later (on April 18, 2011), petitioner was described as improving and "tolerating the immunotherapy" with no intervening sinusitis. Exhibit 7 at 12.

On July 7, 2011, petitioner was treated by her ophthalmologist for a bump and morning "goop" in her left eye. Exhibit 5 at 3. Although she suffered from itchy eyes due to her allergies, she reported that the bump did not itch. She also reported that she treated the same problem in May 2011 with warm compresses and eye drops. Id. Petitioner's ophthalmologist removed the bump[6] and mentioned that petitioner may wish to consider Botox therapy for "the aberrant regeneration of her right seventh nerve." Exhibit 5 at 5.

Medical records from petitioner's allergist, Dr. Wise, indicate she suffered a sinus infection in early September 2011 but was feeling better after ten days of an antibiotic. Exhibit 7 at 11. Petitioner received the influenza vaccination on September 20, 2011 and the TDP vaccination on October 6, 2011. See Exhibits 1-2. She received an immunotherapy injection on October 12, 2011 (exhibit 7 at 24) and a Botox injection on October 14, 2011 (exhibit 5 at 4).

On October 30, 2011, petitioner visited the emergency room at St. Vincent's Indianapolis Hospital with complaints of right side numbness and frequent urination. Exhibit 13 at 97. She indicated her symptoms began on Wednesday, October 26, 2011 after she returned from vacation. Id. at 106. She reported intermitted dizziness after her airplane flight, numbness, and heaviness and but denied any tingling or weakness. Id. at 97. She was told to follow-up with Dr. Caryn M. Vogel at Indiana Neuroscience Associates the next day. Id. at 103.

Petitioner saw Dr. Vogel on October 31, 2011. According to Dr. Vogel's records, petitioner described a "vague sense of dizziness" after returning from her trip. Exhibit

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surgery in 1991 (when 18 years old). Exhibit 7 at 15. Her back surgery (lumbar fusion) occurred in 2007. Exhibit 7 at 10.

[6] Petitioner's ophthalmologist described the bump as a "pyogenic granuloma." Exhibit 5 at 5. Pyogenic means "producing pus." DORLAND'S at 1561. A pyogenic granuloma is "a usually solitary polypoid type of capillary hemangioma (which is neither pyogenic nor a true granuloma)." DORLAND'S at 804

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10 at 4. A few days after that she felt heaviness, numbness, and tingling in her right foot and calf but no pain. As this sensation continued, she "began to note a cold sensation like an ice pack running up and down the leg [and] . . . felt as though she [was] a little off balance" Id. These later symptoms prompted petitioner's trip to the emergency room where she received a normal screening evaluation. Id.

During the visit with Dr. Vogel, petitioner mentioned her recent injections (Botox, influenza, and TDP) and reported some cognitive impairment and greater frequency in urination over the last several months. Exhibit 10 at 4. Dr. Vogel reassured petitioner that her "neurologic evaluation [was] normal but . . . agree[d] we need to rule out secondary causes such as a demyelinating disease or less likely [a] mass or stroke." Id. at 5. Dr. Vogel ordered labs and a brain MRI.[7] Exhibit 10 at 5.

Petitioner visited Dr. Vogel again on November 14, 2011. At that visit, petitioner reported that her symptoms were worsening with the numbness moving to all four extremities, her face, and her head and the addition of twitching and "waves of fatigue." Exhibit 10 at 6. She also reported a reoccurring sinus infection. Noting that all tests to date had been normal, Dr. Vogel ordered an EMG,[8] cervical MRI, and lumbar puncture.[9] Exhibit 10 at 6. Before submitting to this testing, petitioner agreed to wait several weeks to determine if the symptoms would resolve and to take another Z-pack for her sinus infection in the meantime. Dr. Vogel instructed petitioner to "follow up closely with her primary care physician." Id. at 7. In addition to the possibility of multiple sclerosis ("MS")[10] raised by petitioner, Dr. Vogel discussed "other etiologies including connective tissue disease, Lyme disease, fibromyalgia syndrome, and even depression." Exhibit 10 at 6. The results of the EMG performed on December 5, 2011 were normal. Id. at 8.

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[7] MRI, or magnetic resonance imaging, is "a method of visualizing soft tissues of the body." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (32d ed. 2012) ["DORLAND'S"] at 916.

[8] EMG, or electromyogram is used to evaluate patients with muscle weakness. The test monitors the electrical activity of a muscle. MOSBY'S MANUAL OF DIAGNOSTIC AND LABORATORY TESTS (4th ed. 2010) ["MOSBY'S LABS"] at 577-78.

[9] A lumbar puncture, also known as a spinal tap, involves placing a needle in the subarachnoid space of the spinal column to measure pressure and to obtain cerebrospinal fluid for laboratory examination. The presence of blood or bacteria and the amount of glucose or protein present in the spinal fluid may assist in diagnosis of autoimmune and demyelinating disorders and many other diseases. MOSBY'S LABS at 682-88.

[10] Multiple sclerosis is "a disease in which there are foci of demyelination throughout the white matter of the central nervous system, sometimes extending into the gray matter." Symptoms include "weakness, incoordination, paresthesias, speech disturbances, and visual complaint." DORLAND'S at 1680.

On January 6, 2012, petitioner visited her allergist, Dr. Wise, for a follow-up visit regarding her reoccurring sinusitis, specifically mentioning an episode in early October 2011. Exhibit 7 at 10; see id at 11 (September 2011 record ordering follow-up in four months). At that visit, she described her current symptoms as muscle twitching, fatigue, and dizziness. She reported the symptoms began in October 2011 and were resolving. She also reported that her neurological work-up was negative, that she had lumbar fusion surgery in 2007, and that she had received a Botox injection two weeks prior to onset. In notes that appear to have been added later (possibly as petitioner and Dr. Wise discussed her condition), it was noted that petitioner had received the TDP vaccine, had normal MRI and lab results, and was being treated by Dr. Vogel who had prescribed Cymbalta.[11] Dr. Wise questioned the etiology of petitioner's symptoms, speculating whether they were due to GBS or some other viral illness. This is the first mention of GBS in petitioner's records. Dr. Wise indicated petitioner should continue immunotherapy for her mold allergy, questioned whether petitioner should avoid the flu vaccine, and ordered a follow-up appointment in six months. Id.

Petitioner saw Dr. Vogel in March 12, 2012. At that visit, petitioner described her symptoms as improving after she began taking Cymbalta but "not totally gone." Exhibit 10 at 10. She indicated that she sometimes feels a random twitch and tingling all over, that she sleeps poorly and fatigues easily, and that "her muscle pain is worse when the weather is about to change." Id. Dr. Vogel noted that petitioner's December 5, 2011 EMG and all laboratory tests were normal. She indicated that she had discussed the possibility of a lumbar puncture but petitioner "chose to hold off on this test." Id. She observed that petitioner was much calmer than at earlier visits. She noted that petitioner "is accepting of the fact that we may not be able to find a definite etiology and wants to focus more on symptoms management." Id. Dr. Vogel proposed checking petitioner's ferritin levels to determine if "a trial of dopamine" may help her sleep better and recommended that petitioner stay as active as possible. Id.

Petitioner saw Dr. Vogel again six months later on September 10, 2012. Previously, Dr. Vogel had described petitioner's symptoms as diffuse myalgia and paresthesia and chronic dizziness. See, e.g., Exhibit 10 at 10. At this visit, she attributed petitioner's condition to "[p]resumed fibromyalgia syndrome." Id. at 11. Dr. Vogel recorded petitioner's retrospective belief that her symptoms "started after she had had a series of injections including Botox, a tetanus injection and a flu shot."[12] Characterizing petitioner's belief as "interesting," she agreed that "there may have been some sort of autoimmune response" but noted that this was never proven and that

[11] Cymbalta (manufactured by Eli Lilly) is a serotonin and norepinephrine reuptake inhibitor used to treat chronic musculoskeletal pain. PHYSICIAN'S DESK REFERENCE (66th ed. 2012) ["PDR"] at 1603. It has been shown to be effective in treating fibromyalgia. Id. at 1610-11.

[12] Exhibit 10 at 11. Dr. Vogel also noted a personal tragedy petitioner experienced eleven years prior but discounted any effect, noting that petitioner believed she had adjusted and that the prior event did not play a role in her current condition.

petitioner's "workup for secondary causes such as peripheral neuropathy, myopathy or central causes ha[d] been negative." Id. at 12. She indicated that she had explained to petitioner "that to some degree, fibromyalgia is a bit of a 'diagnosis of exclusion'." Id.

Petitioner returned to Dr. Vogel approximately two months later on November 12, 2012. Indicating petitioner suffered from fibromyalgia, Dr. Vogel described her symptoms as improving but "exacerbated by stress (and her menstrual cycle), sleep deprivation, and weather changes." Exhibit 10 at 13. Noting that petitioner regularly exercised and practiced yoga, Dr. Vogel attributed petitioner's improvement to her medication, Cymbalta and Savella.[13] Id. at 14. She again mentioned that petitioner's neurological workup for secondary causes such as MS and myopathy were negative. Because petitioner wished to try a higher dose of Savella, Dr. Vogel instituted a gradual increase in dosage. Id. At this visit, petitioner also complained about migraine headaches she had been experiencing in a recurrent pattern for years but chose to defer any preventive medication. Id. at 13-14.

Over the next six months, petitioner visited Dr. Vogel two more times regarding her symptoms. On February 11, 2013, Dr. Vogel noted that petitioner was taking melatonin to help her sleep and had experienced a definite improvement on the higher dosage of Savella. Exhibit 10 at 15-16. Because of concerns regarding weight gain, Dr. Vogel instructed petitioner to discontinue the Cymbalta. When petitioner returned on May 20, 2013, Dr. Vogel indicated there was no change in her weight but a definite improvement in her level of fatigue which petitioner attributed to an intensive vitamin therapy she had begun. Id. at 18. She recommended petitioner continue her vitamin therapy and Savella. Id. at 19. It appears the May 2013 visit was the last time petitioner was seen by Dr. Vogel.

On July 24, 2013, petitioner began seeing a chiropractor. On her intake form, she listed numbness and twitching as her primary complaint and fibromyalgia as her secondary complaint. Exhibit 4 at 10. She attributed her condition to her flu and tetanus vaccinations and Botox injections. Id. She continued to see the chiropractor through March 2014. See id. at 9. In the records from these visits, petitioner's condition was initially described as bilateral neck pain, then as diffuse pain with an unknown trigger, pain at a manageable level, and finally fibromyalgia pain beginning in February 2014. Id. at 1-9.

Petitioner sought treatment from a new neurologist, Dr. McGarvey, during the fall of 2013, approximately two years after her symptoms began. At her first visit (on November 4, 2013), petitioner listed her chief complaint as fibromyalgia and indicated debilitating pain was her biggest concern. Exhibit 12 at 32. She reported that her pain was triggered by her menstrual cycle and the weather.

When providing her history, petitioner reported that she received a flu and tetanus vaccination on the same day, a Botox injection to treat her right eye Bell's palsy,

[13] Savella (manufactured by Forest Pharmaceuticals) is used to treat fibromyalgia. See www.savella.com (last visited on Nov. 30, 2015).

weakness and numbness in the left calf and neck, and dizziness and difficulty with her vision. "These symptoms slowly dissapated [sic] and she was left with diffuse muscle pain in arms and legs, which has gotten better [but she still had] pain in [her] neck and jaw." Id. Petitioner also reported that she had an EMG in the spring of 2012 after her dizziness, fasciculation,[14] and numbness had gone. Id. A comparison of this information to that found in the medical records created closer in time to the onset of petitioner's condition showed several inaccuracies in the information petitioner provided to Dr. McGarvey.[15]

Based on this history, Dr. McGarvey concluded petitioner "[l]ikely had GB, now with residual symptoms." Exhibit 12 at 35. She ordered a second EMG and referred petitioner to an ophthalmologist for her eye issues. Id.

When petitioner visited the ophthalmologist on November 20, 2013, she reported a history of GBS and fibromyalgia. Exhibit 3 at 5. Her examination was normal with no edema observed. Id. at 2.

The results of the second EMG performed on November 22, 2013 were normal but Dr. McGarvey discounted this finding since the EMG was performed "far out" from when her symptoms occurred. Exhibit 12 at 29; see id. at 31 (EMG results). Dr. McGarvey again opined that petitioner was experiencing residual symptoms of GBS. Id. at 30. Theorizing that petitioner's snoring may be contributing to daytime insomnia and fatigue, Dr. McGarvey recommended a sleep study. Id.

Petitioner underwent a sleep study on December 19, 2013. The study indicated she suffered from moderate sleep apnea but concluded not all of petitioner's symptoms could be explained by this finding. Exhibit 12 at 27. When Dr. McGarvey saw her the next day, she noted petitioner was sleeping better due to her medication. Id. at 22. At this visit, Dr. McGarvey recommended that petitioner receive no more flu vaccinations due to her history of GBS. Id. at 25.

In February 2014, petitioner visited her allergist, Dr. Wise. He reported that she was doing well with no sinusitis since her last visit and would continue her

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[14] Fasciculation is "the formation of fasciculi" or "a small local contraction of muscles, visible through the skin, representing a spontaneous discharge of a number of fibers innervated by a single motor nerve filament." DORLAND'S at 682.

[15] First, petitioner did not receive the flu and tetanus vaccinations on the same day. See Exhibits 1-2. Second, petitioner's weakness and numbness occurred in her right not left leg and foot. See Exhibit 13 at 97. Most importantly, petitioner's earlier EMG (the results of which were normal) occurred on December 5, 2011 approximately one month after petitioner's symptoms began and while she was experiencing them. See Exhibit 10 at 8, 10. Although Dr. McGarvey mentioned this earlier EMG, she did not discuss its results. Thus, it is not clear whether Dr. McGarvey even knew that the results were reported to be normal.

immunotherapy. Exhibit 7 at 6. Reporting that petitioner suffered an episode of GBS after receiving the flu vaccine in 2009, he indicated "the influenza vaccine is contraindicated in her case." Id.

In December 2013, petitioner saw her gynecologist for abnormal bleeding between periods. See Exhibit 6 at 13. The results of a January 8, 2014 pap smear and March 20, 2014 endometrium biopsy were normal. Id. at 12, 17. At a March 20, 2014 appointment with her gynecologist, petitioner included a history of fibromyalgia with onset in 2011. Id. at 13.

Petitioner saw Dr. McGarvey again in May and July 2014. At both visits, petitioner reported improving pain but continued fatigue and some dizziness. Exhibit 12 at 5, 12. For the first time, she also reported an inability to sing. Id. At the July 15, 2014 visit, Dr. McGarvey prescribed a small dose of depokote.[16] Id. at 8.

Updated medical records from petitioner's allergist, Dr. Wise, show she continued to receive immunotherapy injections in 2014 and early 2015. See, e.g., Exhibit 16 at 22. At an August 18, 2014 visit, Dr. Wise reported that petitioner continued to get good results from her immunotherapy. Id. at 10. He added that petitioner had Tamiflu on hand in case she got the flu. Notes from a February 16, 2015 visit mention GBS, deep muscle pain, and fibromyalgia, describing petitioner as "tearful when discussing GB issue." Id. at 20. The record also contains a recommendation that petitioner receive no further flu vaccinations and an entry indicating petitioner requested such a note for her attorney. Id. Both original and updated records from Dr. Wise include a "Problem List Sheet" which contains an entry regarding GBS resulting from a flu vaccination. Exhibits 7 at 3; 16 at 5. The sheet, however, contains no further information and is not dated. Id.

On June 30, 2015, petitioner filed a letter from Dr. McGarvey to petitioner's counsel (dated June 22, 2015). Citing the instance of GBS related to vaccinations reported in medical literature, Dr. McGarvey opined "it sounds as if [petitioner] had a neurologic complications secondary to [one] or more of the combination of vaccines that she had." Exhibit 17 at 1. She qualified her opinion by noting that she "was not involved in [petitioner's] initial care" and thus, her opinion was "based on [petitioner's] history and symptoms." Id. Dr. McGarvey also opined that petitioner's symptoms were consistent with GBS but added that it was "unfortunate that we do not have a lumbar puncture from her original presentation." Id. at 2. In drawing these conclusions, Dr. McGarvey relied on facts which are contradicted by the more contemporaneously created medical records. For example, she again reported that petitioner's first EMG was performed in the spring of 2012 rather than on December 5, 2011 as the records show. Id. at 1. Like Dr. Wise, Dr. McGarvey recommended petitioner receive no further flu vaccinations. Id. at 2.

[16] Depakote is a drug used to treat seizure disorders. DORLAND'S at 490, 558.

III. Applicable Legal Standards

Under the Vaccine Act, petitioner may prevail on her claim if she has "sustained, or endured the significant aggravation of any illness, disability, injury, or condition" set forth in the Vaccine Injury Table (the Table). § 11(c)(1)(C)(i). The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. § 14(a). If petitioner establishes that she has suffered a "Table Injury," causation is presumed.

If, however, petitioner suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, she must prove that the administered vaccine caused injury to receive Program compensation. § 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, petitioner must prove her claim by preponderant evidence. § 13(a)(1)(A). This standard is "one of . . . simple preponderance, or 'more probable than not' causation." Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1279-80 (Fed. Cir. 2005) (referencing Hellebrand v. Sec'y of Health & Human Servs., 999 F.2d 1565, 1572-73 (Fed. Cir. 1993). The Federal Circuit has held that to establish an off-Table injury, petitioner must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1351 (Fed. Cir 1999). Id. at 1352. The received vaccine, however, need not be the predominant cause of the injury. Id. at 1351.

The Circuit Court has indicated that petitioner "must show 'a medical theory causally connecting the vaccination and the injury'" to establish that the vaccine was a substantial factor in bringing about the injury. Shyface, 165 F.3d at 1352-53 (quoting Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that "[t]here must be a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury.'" Id. The Federal Circuit subsequently reiterated these requirements in its Althen decision. See 418 F.3d at 1278. Althen requires a petitioner

> to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of Althen must be satisfied. Id. Close calls regarding causation must be resolved in favor of the petitioner. Id. at 1280.

Petitioner is not required to eliminate alternative causes when establishing his prima facie case. Doe 11 v. Sec'y of Health & Human Servs., 601 F.3d 1349, 1357-58 (Fed. Cir. 2010); de Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). To support an argument regarding causation, petitioner may,

however, introduce evidence of the lack of an alternative cause. Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1149-50 (Fed. Cir. 2007). Respondent also may introduce evidence of the prescence of an alternative cause to rebut evidence regarding causation. Doe 11, 601 F.3d at 1358; de Bazan, 639 F.3d at 1353.

Once petitioner has established a prima facie case, the burden shifts to respondent to show by preponderant evidence that petitioner's injury was "due to factors unrelated to the administration of the vaccine." § 13(a)(1); see also DeBazan, 639 F.3d at 1352-54; Walther, 486 F.3d at 1150.

IV. Analysis of Petitioner's Claim

Petitioner maintains that she suffered GBS causally related to the influenza vaccination she received on September 20, 2011 and the TDP vaccination she received on October 6, 2011. Motion for a Decision on the Record at 1. To support her claim, petitioner relies solely on the medical records filed and the June 22, 2015 letter from Dr. McGarvey.

Respondent opposes compensation in this case and maintains that the petition should be dismissed. Response at 1. She argues that petitioner's correct diagnosis is fibromyalgia and that petitioner has not established that she suffered from GBS. Response at 5. She further argues that petitioner has failed to prove "that her alleged injury, whether it is GBS, fibromyalgia, or any other condition, was caused in fact by either her flu or DTP vaccines." Id. at 6.

1. The Alleged Injury

The Federal Circuit has held that, when the injury itself is in dispute, "it was appropriate . . . for the special master to first determine which injury was best supported by the evidence presented in the record before applying the *Althen* test so that the special master could subsequently determine causation relative to injury." Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). "[U]nder *Broekelschen*, identification of a petitioner's injury is a prerequisite to an *Althen* analysis of causation. Lombardi v. Sec'y of Health & Human Servs., 656 F.3d 1343, 1352 (Fed. Cir. 2011).

In this case, the record does not support petitioner's allegation that she suffered from GBS. GBS is mentioned in only a few places in the medical records filed. Petitioner's allergist, Dr. Wise, first suggested that petitioner's symptoms may be due to GBS or some viral illness in early January 2012. Exhibit 7 at 10. He did not opine further and did not mention the possibility again until more than two years later on February 17, 2014 after petitioner began seeing Dr. McGarvey. See id. at 6. At that visit, Dr. Wise prescribed Tamiflu for petitioner because "the influenza vaccine [was] contraindicated in her case" due to an earlier episode of GBS after the flu vaccine in 2009. Id. There is no indication that Dr. Wise (an allergist) reached this conclusion himself. Rather, it appears that he simply accepted the diagnosis and assertion regarding causation provided to him by petitioner. See Exhibit 12 at 35. Furthermore,

he erroneously indicates petitioner suffered GBS in 2009, rather than 2011. Exhibit 7 at 6.

On November 20, 2013, one of petitioner's ophthalmologists, Dr. Brazus, also recorded a history of GBS as well as fibromyalgia. Exhibit 3 at 5. Like Dr. Wise, Dr. Brazus appears to be reciting a history provided to him by petitioner. It is important to note that neither Dr. Wise nor Dr. Brazus are neurologists and likely would not diagnosis a condition such as GBS but would refer petitioner to a neurologist to determine if such a diagnosis was appropriate.

Dr. McGarvey is the only physician who actually opined that it is likely petitioner suffered from GBS, and she did not begin treating petitioner until two years after her symptoms began. See Exhibit 12 at 35. Although Dr. McGarvey is a neurologist, she acknowledged that she "was not involved in [petitioner's] initial care" and based her opinion on the history and symptoms described to her by petitioner. See Exhibit 17 at 1. According to Dr. McGarvey, petitioner was no longer suffering from GBS when Dr. McGarvey first saw her but only the "residual symptoms" of GBS. Exhibit 12 at 35.

Furthermore, Dr. McGarvey based her opinion on the medical history provided to her by petitioner. See note 15. There is no evidence indicating that Dr. McGarvey ever reviewed Dr. Vogel's medical records herself or saw the results of the December 5, 2011 EMG. Even Dr. McGarvey acknowledges the weak nature of the evidence, indicating it is "unfortunate" a lumbar puncture was not performed. Exhibit 17 at 2.

On the other hand, petitioner's initial neurologist, Dr. Vogel (who treated petitioner at the time of her initial symptoms and for the following two years and ordered the December 5, 2011 EMG) never mentioned the possibility that petitioner suffered from GBS. In fact, she consistently noted that petitioner's neurological work-up was negative and there was no indication petitioner suffered from any neuropathy. See, e.g., Exhibit 10 at 12. Dr. Vogel subsequently diagnosed petitioner with fibromyalgia and treated her accordingly. Petitioner's improvement was attributed to the medication Dr. Vogel prescribed to treat her fibromyalgia. See, e.g., Exhibit 10 at 14.

The opinion of a treating physician is favored because "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect shows that the vaccination was the reason for the injury." Capizzano v. Sec'y, Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006) (citations and internal quotation marks omitted). In this case, however, Dr. Vogel is the neurologist who treated petitioner during the time when Dr. McGarvey believes she suffered from GBS. It was Dr. Vogel who observed petitioner's symptoms, ordered the appropriate tests, and determined petitioner's treatment.

In forming her opinion, Dr. McGarvey relied upon information provided to her two years later by petitioner which conflicts with the information found in the contemporaneously created medical records. "It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight." Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. 726, 733 (1991) aff'd, 968 F.2d 1226 (Fed.Cir.1992), cert. denied, 506 U.S. 974, 113 S.Ct. 463,

121 L.Ed.2d 371 (1992) (citing United States v. United States Gypsum Co., 333 U.S. 364, 396 (1947)). Based on this later provided, erroneous information and occurring after she believed petitioner's condition had resolved, Dr. McGarvey's diagnosis should not be given the same weight.

In light of Dr. Vogel's contemporaneous diagnosis, Dr. McGarvey's opinion two years after the fact is not sufficient to establish petitioner suffered from GBS. And Drs. Wise and Brazus relied on representations by petitioner shortly after Dr. McGarvey opined petitioner had suffered from GBS. As the neurologist treating petitioner during onset and the following two years, Dr. Vogel provides the more trustworthy diagnosis.

2. Causation

In Lombardi, the Federal Circuit held that "[i]n the absence of a showing of the very existence of any specific injury of which petitioner complains, the question of causation is not reached." 656 F.3d at 1353. The Circuit explained that "the statute places the burden on the petitioner to make a showing of at least one defined and recognized injury." Id. Petitioner cannot prove that her injury was caused by the vaccinations she received when she cannot establish that she suffered an injury in the first place. In this case, petitioner has failed to establish that she suffered from GBS. Thus, it follows that she cannot prove that she suffered GBS which was caused by the vaccinations she received.

Even if she had established that she had GBS, petitioner would still have to prove that her injury was vaccine caused by satisfying the three pronged Althen test. She must establish by preponderant evidence that the vaccinations she received caused her injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278.

Petitioner has provided no expert report with a medical theory causally connecting her injury to the vaccinations she received. Similarly, she has provided no evidence of a proximate temporal relationship between the vaccinations she received and the symptoms she suffered. She has failed to satisfy the first and third prongs of the Althen test.

The only evidence petitioner has provided to show a logical sequence of cause and effect connecting the vaccinations she received to the symptoms she suffered is predicated on the assertion that she suffered from GBS. Thus, petitioner has failed to satisfy the second Althen prong as well.

Petitioner has not provided preponderant evidence that her symptoms were caused by the vaccinations she received. Therefore, she has failed to satisfy all three Althen prongs.

V. Conclusion

Petitioner has failed to offer the opinion of a medical expert, and the medical records filed do not support her allegations. She has failed to demonstrate that she suffered from GBS and that her condition was caused the vaccination she received.

Petitioner has failed to establish that she is entitled to compensation under the Vaccine Act. **This case is dismissed for insufficient proof.**

The clerk of the court is directed to enter judgment in accordance with this decision.[17]

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master

[17] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party filing a notice renouncing the right to seek review.